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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/537,118	03/29/2000	Harry Dugger III	PHCO3.0-008	7521

1815 7590 03/18/2002

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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT PAPER NUMBER

1616

DATE MAILED: 03/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/537,118

Applicant(s)

DUGGER, HARRY

Examiner

Mina Haghighatian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagy et al (5,047,230) in view of Purewal et al (5,766,573).

Nagy et al teaches aerosol composition comprising nitroglycerin as active ingredient. The said aerosol is mainly administered translingually, sublingually or buccally to the organism, to induce a high blood level of nitroglycerin within a short time (col. 2, lines 16-35).

Nagy explains that the aerosol composition may contain from 0.1 to 4% by weight of the active agent, nitroglycerin. The compositions comprise polyethylene glycol and/or polypropylene glycol. The commercially available polyethylene glycol is Carbowax®. The compositions can comprise 0.8 to 1.0% by weight of nitroglycerine, 55 to 85% by weight of ethyl alcohol and 15 to 45% by weight of polyethylene glycol, propylene glycol and/or butylenes glycol, which meets limitations of claim 1(a) (col. 2, line 66 to col. 3, line 15). Nagy discloses these concentration ranges in examples 1-7. Nagy also discloses that fatty carriers such as saturated fatty acid triglycerides (Mygliol®) have been used in nitroglycerin compositions (col. 2, lines 1-4).

Nagy teaches the compositions to include additives such as flavouring agents e.g. sweeteners like sorbitol and saccharine and aroma substances such as menthol, peppermint oil, citrus oil etc (col. 3, line 16-22).

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Nagy et al lacks specific teachings on other active agents and on the propellants.

Purewal et al teaches medicinal aerosol formulations. The suitable propellants are saturated hydrocarbon propellants such as n-butane, iso-butane, pentane etc, and high polarity propellants such as propellant 134a (col. 1, line 49 to col. 2, line 50).

Purewal discloses suitable medicaments to include analgesics, bronchodilators, antihistamines, antibiotics, hormones, alkaloids, enzymes, aninal preparations, etc. examples of these medicaments are: morphine, glucagons, epinephrine, codeine, terbutaline, salbutamol, flunisolid etc, (col. 5, lines 43-64).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have substituted medicaments such as terbutaline, as taught by Purewal, for nitroglycerine aerosol composition of Nagy with the reasonable expectations of preparing more therapeutic routes of administration for more medicaments because of need for fast absorbing medications and ease of administration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 703-308-6330. The examiner can normally be reached on core office hours.

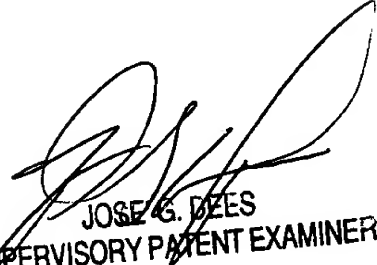
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghighatian  
March 8, 2002

  
JOSE G. DEES  
SUPERVISORY PATENT EXAMINER

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